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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913
29052 7590 04/27/2007 SUTHERLAND ASBILL & BRENNAN LLP 999 PEACHTREE STREET, N.E. ATLANTA, GA 30309			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3767	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/654,761

Applicant(s)

AUSIELLO ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-21, 24, 27, 32 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-21, 24, 27, 32 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/6/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6 April 2007 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1,12,17-20,24,27,32, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 6,349,232) in view of Cheikh (US 5,660,846). Gordon teaches and implantable (Col 4 lines 45-51) medical device for controlled delivery of a medical substance with a plurality of reservoirs (270), a release system (medical substance), with discrete reservoir caps (not labeled, Figures 9-11D), which are disintegrated by means of electrothermal ablation (resistive heating by 272/271, see Cols 8 and 9). Sensor (169) may also be included in the device. Gordon does not disclose the delivery of parathyroid hormone.

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Cheikh teaches the delivery of a parathyroid hormone from an implantable device (Col 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose the parathyroid hormone to deliver from the device of Gordon in order to provide appropriate medical treatment to the patient.

4. Claims 2-10 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon and Cheikh as applied above, and further in view of Rubin, et al., "The Potential of Parathyroid Hormone as a Therapy for Osteoporosis," Int. J. Fertil. 47(3): 103-15 (2002) (cited by applicants; hereinafter "Rubin").

Gordon and Cheikh teach the device and method as above, but fail to teach the details of the parathyroid treatment.

Rubin suggests the use of parathyroid hormone to treat osteoporosis. Rubin discusses dosage, length of therapy and the use of bone resorption inhibitors as well. It would have been obvious to one of ordinary skill in the art to modify the system disclosed by Gordon and Cheikh, by including parathyroid hormone as the release system in order to provide therapy for those suffering from osteoporosis.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon and Cheikh, further in view of U.S. Patent No. 6,011,011 to Hageman.

Gordon and Cheikh disclose the claimed invention as shown above except for an excipient of polyethylene glycol. Hageman teaches the use of polyethylene glycol as an excipient with parathyroid hormone. See col. 3, line 28 through col. 4, line 12. It would have been obvious to one of ordinary skill in the art to modify the invention of Gordon

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and Cheikh and Rubin by including polyethylene glycol as an excipient in order to provide a sustained or prolonged release of the hormone.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth R. MacNeill*  
4/16/07

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*